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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/711,859	10/11/2004	Nitesh Ratnakar		5858

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BOYLE FREDRICKSON S.C.
840 North Plankinton Avenue
MILWAUKEE, WI 53203

EXAMINER

LEUBECKER, JOHN P

ART UNIT	PAPER NUMBER
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3739

NOTIFICATION DATE	DELIVERY MODE
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03/11/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@boylefred.com

Office Action Summary	Application No. 10/711,859	Applicant(s) RATNAKAR, NITESH	
	Examiner John P. Leubecker	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,10,12,13,15,16,43,44,47-50,54-57 and 61-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,10,12,13,15,16,43,44,47-50,54-57 and 61-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 9, 2008 has been entered.

Claim Objections

2. Claim 48 is objected to because of the following informalities: claim 48 is identified as being “withdrawn” but it appears that it was intended to be canceled since the subject matter of this claim has been incorporated into claim 47. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 3, 10, 12, 13, 15, 16, 43, 44 and 67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites that the first and second images (which

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are obtained from directions that are 180 degrees apart from each other) define overlapping forward and rear images of the same hollow organ (assuming that the images are simultaneously obtained, per Applicants remarks, page 11, lines 1-3, filed December, 9, 2008). The specification fails to disclose that the first and second images ever simultaneously “overlap” when there is a 180 degree difference between them. Although such overlapping of images could be possible, the occurrence of this would depend on the angle of the field of view of each imaging lens, the focal distance of each imaging lens, the distance the second lens is extended past (distally) the first lens, or the point in time that each of the images are taken (for instance, a first image can be taken by the shaft and such could be moved to a position at a later point in time to allow the catheter to image the same spot from a direction 180 degrees from the first image). Nothing in the specification indicates that Applicant contemplated these parameters or any other parameters that would allow for the overlapping of images as claimed.

Dependent claims inherit those defects.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 3, 10, 12, 13, 15, 16, 43, 44, 47-50 and 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 1, the phrase “the second image being dependent on the first image” is indefinite as to its intended meaning since the nature of the “dependency” is unclear.

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As to claim 48, if this claim were not "withdrawn" (note objection above), the claim would not be further limiting since redundantly recites subject matter of claim 47.

As to claim 67, term "actuator" lacks antecedent basis. It appears that this claim should depend from claim 10 which first mentions the actuator.

As to claim 47, the phrase "the first and second images representing a common field of view within the hollow body component" is indefinite as to its intended meaning. If "common field of view" is taken as the same field of view, this does not appear to be possible since the fields of view of the first and second images are 180 degrees apart. However, the term is referring to commonality of the subject matter in the field of view (e.g., both images show a hollow body component, yet different parts of one), then this would be understandable (yet unnecessary since the mere fact that both images are taken within the hollow body component inherently provides this commonality). Clarification is required.

Dependent claim inherit those defects.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. Claims 1, 3, 10, 12, 13, 43, 44, 47, 49, 50, 54-57, 61-63, 66 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaiya (U.S. Pat. 5,178,130) in view of Torii (U.S. Pat. 6,482,149).

As to claims 1, 47, 54 and 55, Kaiya discloses a shaft/endoscope (6a, Fig.2) extending along a longitudinal axis and having distal and proximal ends and defining a hollow channel therethrough (16); a first image lens (28a, Fig.1) fixedly attached to the distal end of the insertion tube for receiving a first image in a first direction, the first direction being a generally forward circumferential view that is parallel to the longitudinal axis of the shaft (note Fig.1); a catheter (endoscope 2b) receivable in the hollow channel of the shaft for extension and retraction relative to the distal end of the shaft (note Fig.2, col.3, lines 46-54); and a rear view module/second image lens (28b, Fig.1) adjacent the distal end of the catheter, the second image lens movable in a second direction with respect to the first image lens when extending beyond the first lens so as to receive a second image in the second direction. Kaiya teaches that the shaft (6a) and catheter (2b) comprises curvable sections (14 a,14b, col.3, lines 40-45), as opposed to merely a flexible section (15a,15b). The Examiner takes the position that this 'curvable section' anticipates a steering mechanism which will actively allow curving in a desired direction and thus allow the second direction to be at a predetermined angle to the first direction.

Kaiya fails to provide any particulars as to the curvable sections of the endoscope/catheter. Torii is one of many references which evidences what is known in the endoscope art. Torii teaches an actuator mechanism for bending the curving section (22, Fig.1) of an endoscope in four perpendicular directions comprising at least first and second wires (54, Fig.2, col.9, lines 23-25). The curving section can be bent well over 180 degrees from the

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longitudinal axis (Fig.19). Given the lack of disclosure as to the particulars of the curvable section in Kaiya, it would have been obvious to one of ordinary skill in this art to have turned to the prior art to "fill in the gaps" when reducing the Kaiya device to practice. Indeed, use of the known curvable section as taught by Torii for the curvable section of Kaiya would have been part of the ordinary capabilities of a person skilled in this art. Use of such known curvable part would allow the angle between the first direction and second direction to be at least 180 degrees, allowing the capability of providing overlapping/common forward and rearward images of the same hollow organ (for instance, a first image can be taken by the first endoscope and such could be moved to a position at a later point in time to allow the catheter to image the same spot from a direction 180 degrees from the first image). As to claim 3, since the first and second lenses are used simultaneously (Fig.2), they inherently receive images simultaneously.

As to claims 10, 49 and 56, and as mentioned above, the Examiner takes the position that, in order to be 'curvable', each of the endoscope and catheter shafts must inherently have some kind of active mechanism to provide the curvable function. This mechanism would anticipate an 'actuator' as broadly as claimed. However, the teachings of Torii would also teach an actuator.

As to claims 12 and 61, note imaging device (29b) and processor (32b) in Figure 1.

As to claims 13 and 62, display screens (5a,5b) constitute a display screen for displaying the first and second images. Also note col.9, line 66 to col.10, lines 4.

As to claim 43, 50 and 57, the curvable section/actuator taught by Torii include first and second wires (54, Fig.2)

As to claim 63, Kaiya teach that the both endoscopes (2a,2b) can be fiberscopes with externally fitted camera (col.9, lines 61-65). As evidenced by Karasawa et al. (U.S. Pat.

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5,196,928), a fiberscope with external camera (2b, Fig.5 of Karasawa et al.) includes an eyepiece (9d, Fig.5, col.5, line 63 to col.6, line 24).

As to claims 44, 66 and 67, the wires (54) of Torii would anticipate a "bending structure disposed at the distal end of the catheter" that "urges the catheter into the second direction upon exit from the hollow channel".

9. Claims 15, 16, 64 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaiya in view of Torii and further in view of Yoon (6,066,090).

Kaiya in view of Torii disclose the device as described above and that the illumination for both the endoscopes (2a,2b) is provided by an optical fiber waveguide (17a,17b). Thus, Kaiya fails to disclose one or more illumination bulbs disposed on the distal tip of the catheter. Yoon et al. discloses a similar endoscope system in which either of the endoscopes (14, 16 or 18) can include an optical wave guide for illumination but alternatively can include LEDs or incandescent bulbs located at the distal end (col.5, lines 1-12). Since both Kaiya and Yoon teach endoscope devices and illumination sources, it would have been obvious to one of ordinary skill in the art to have substituted one alternative illumination arrangement for another to achieve the predictable result of providing illumination to the field of view. One would be motivated to use an illumination bulb (e.g., LED) at the distal end to eliminate the need optical fibers to extend through the shaft, which fibers attenuate light and are capable of breaking.

Inherently, use of any electrical bulb source (i.e., LED) will require a connection to a power source.

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10. Claims 1, 3, 10, 12, 13, 15, 16, 43, 44, 47, 49, 50, 54-57, 61, 62, 64-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (U.S. Pat. 6,066,090).

Yoon discloses a shaft/endoscope (12,14, Fig.1) extending along a longitudinal axis (e.g., z-axis in Fig.4) having a distal end (14) and a proximal end (12) comprising a first lens (36, Fig.2) fixedly attached at the distal end which can receive a first image of a circumferential view of a forward direction (in the condition that it is not bent, note 44 Fig. 8 for example, it would be along the longitudinal axis) and a catheter (18, Figs.1,2) including a rear view module/second lens (36 on 18) for simultaneously receiving a second image at a predetermined angle to the first direction (in the condition that it is bent, note 46 in Figure 4 for example). The catheter (18) is receivable in a hollow channel (note channel of shaft 12 that accommodates 18, Fig.1). The distal end of the shaft (14) and the catheter (18) are independently steerable via an actuator up to approximately 180 degrees (note col.5, line 51 to col.6, line 34, which incorporates Shockey, U.S. Pat.5,168,864 and Hibino et al., U.S. Pat. 4,982,725, by reference as showing a suitable steering control mechanisms; note col.2, lines 20-30 of Shockey which teaches 180 degree deflection; and Figure 1, elements 10 and 13 of Hibino et al., col.8, lines 4-22 which show multiple control wires and bending in four perpendicular directions). Any of the steering mechanisms disclosed or incorporated by reference by Yoon would anticipate a "bending structure disposed at the distal end of the catheter" that "urges the catheter into the second direction upon exit from the hollow channel". Note that all lenses operatively connect to an image processor (26) and monitor (27) (Fig.1). The rear view module can include a LED (54b) which is a "bulb" and requires a power source. Steering up to 180 degrees (mentioned above) would conceivably allow for overlapping/common forward and rearward images of the same

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hollow organ (for instance, a first image can be taken by the first endoscope and such could be moved to a position at a later point in time to allow the catheter to image the same spot from a direction 180 degrees from the first image).

It would appear that, due to the fact that each endoscope branch (14, 16 and 18, Fig.1) is individually and separately steered and individually rotatable about their respective longitudinal axes (col.4, lines 27-37), and the fact that no structure is disclosed that secures the branches in any particular manner to the shaft (12), that each endoscope branch would be capable of extension and retraction with respect to the shaft (12). However, Yoon fails to explicitly mention such capability. If not inherently contemplated by Yoon, it would have been obvious to one of ordinary skill in the art to have allowed the endoscope branches (14,16,18, Fig.1) to also be capable of moving in the direction of the longitudinal axis, and more advantageously, independently movable in that direction. This would provide an extra degree of freedom to the independently steerable and rotatable branches, thus making each branch easier to maneuver as desired. Therefore, this would anticipate the limitation of the catheter being reversibly received within the channel of the shaft or receivable in the shaft for extension or retraction.

Response to Arguments

11. Applicant's arguments filed December 9, 2008 have been fully considered but they are not persuasive.

Regarding the Kaiya reference, Applicant argues that both endoscopes (which anticipate the shaft and catheter of the claims) are "side view" endoscopes. The Examiner respectfully disagrees. All the figures in this reference indicate that they are both "forward view" endoscopes

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and nothing in the disclosure even suggests a “side view” embodiment. In addition, it appears that Applicant does not believe that the lens (28a) is “fixedly attached” to the distal end of the endoscope (2a). There is no logical reason for this belief and Applicant provides no evidence of such. In addition, Applicant argues that the endoscope of Kaiya does not enable simultaneous circumferential forward and rear views along an axis parallel to the longitudinal axis of the parent endoscope. However, given the fact that, in view of Torii, both endoscopes of Kaiya would be capable of bending 180 degrees, the system of Kaiya would also be capable of providing forward and rear views along the same axis 180 degrees apart (e.g., by keeping the first endoscope 2a straight and bending the second one (2b) 180 degrees). This of course is all assuming that the angle of the field of view of each imaging lens, the focal distance of each imaging lens, and the distance the second lens is extended past (distally) the first lens cooperate to allow such overlapping. It is noted that the claim does not call for the images to be “simultaneously” obtained, but since the claim language could encompass this, the issue of whether or not such feature was contemplated is set forth above.

Regarding Yoon, Applicant disagrees with the interpretation that the hollow body and one flexible branch would be equivalent to the shaft of the present invention. Whether they are equivalent or not was not or is not the issue. Whether they meet the claim limitations of the shaft is the issue. And the Examiner takes the position that the structure of the hollow body and one flexible branch does meet the analogous limitations in the claims. In addition, similar to the Kaiya reference, the Examiner also takes the position that there is no reason to believe that the lens (36) at the distal end of the shaft (14) is not fixedly attached. Furthermore, contrary to

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Applicant's belief, it was previously shown by the Examiner that the shaft (12,14) and catheter (18) have independent steering mechanisms.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Leubecker whose telephone number is (571) 272-4769. The examiner can normally be reached on Monday through Friday, 6:00 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John P. Leubecker/
Primary Examiner
Art Unit 3739

jpl